

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION**

DILORENZO BIOMEDICAL, LLC,

Plaintiffs,

v.

LIVANOVA, INC. and LIVANOVA USA,  
INC.,

Defendants.

Civil Action No. 4:23-cv-1800

Patent Case  
Jury Trial Demanded

**DEFENDANTS' MOTION TO DISMISS**  
**PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(7)**

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<b>Exhibit</b>	<b>Description</b>
A	2004-03-31 NeuroBionics Founder Agreement
B	2004-12-14 NeuroBionics Amended and Restated Founder Agreement
C	2014-12-14 Dr. DiLorenzo Assignment to NeuroBionics
D	2005-02-08 NeuroBionics Proprietary Information, Inventions Assignment and Noncompete Agreement
E	2005-05-23 Exclusive License Agreement between BioNeuronics and DiLorenzo
F	2006-04-18 Separation Agreement between Dr. DiLorenzo and BioNeuronics
G	Feb 2009–Feb 2013 emails between Dr. DiLorenzo and Cyberonics
H	2012-11-22 Dr. DiLorenzo email to Cyberonics
I	2013-02-11 Bill of Sale (Cyberonics Acquisition of NeuroVista)
J	2013-03-13 email to Cyberonics from Dr. DiLorenzo
K	Aug 2013–Nov 2013 emails between Dr. DiLorenzo and Cyberonics
L	2020-11-18 Letter to Rowell from Gibson (Dr. DiLorenzo’s attorney)
M	June 2022–Aug 2022 emails between Dr. DiLorenzo and LivaNova
N	2022-12-01 Option Agreement between Dr. DiLorenzo and LivaNova

## I. INTRODUCTION

The Asserted Patents are owned by the Defendants, LivaNova. Dr. Daniel J. DiLorenzo, the individual behind Plaintiff, DiLorenzo Biomedical LLC (“DiLorenzo”), assigned the asserted ’813 patent and any provisional applications, continuations, and continuations in part naming the ’813 patent as a parent case to LivaNova’s predecessor-in-interest in 2004 [REDACTED] [REDACTED]. After this assignment, Dr. DiLorenzo made another assignment to the same entity, relating more broadly to inventions in the field of neurodiagnostics and/or neuromodulation. The ’813, and the two other asserted patents, the ’787 and ’880 patents, fall under both assignments. In a 2005 agreement between LivaNova’s predecessor-in-interest and DiLorenzo, LivaNova granted back a license to the ’813 patent and its progeny for use in the field of treating obesity and metabolic disorders (“License Grant”).

Dr. DiLorenzo ultimately separated from LivaNova’s predecessor-in-interest, but for the past fifteen years, the parties maintained a line of communication. In every pertinent correspondence between the parties, Dr. DiLorenzo unequivocally recognizes that his rights in the Asserted Patents are limited and that he **does not** have rights to the Asserted Patents in the field of epilepsy treatment. In fact, just over a year ago Dr. DiLorenzo attempted to purchase the Asserted Patents **from LivaNova**. LivaNova refused and now DiLorenzo relies on an improper read of the License Grant in a baseless attempt to assert the very patent rights Dr. DiLorenzo contracted away. DiLorenzo’s interpretation of the License Grant is not grounded in the Agreement itself, nor when viewed in the context of the other relevant documents, the history of the parties, and their correspondence following the execution of the License Grant. DiLorenzo’s claims cannot stand for at least two reasons.

*First*, under well-settled Supreme Court case law, a licensee cannot sue for patent infringement without joining the patent owner if the license grants merely “an undivided part or

share of th[e] exclusive right [granted under the patent].” *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383–84 (Fed. Cir. 2015) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891)). DiLorenzo’s own Complaint admits DiLorenzo is merely a licensee in a Field of Use. Dkt. 1, ¶ 15. Because DiLorenzo failed to join LivaNova as a plaintiff in this suit, DiLorenzo lacks standing to bring this suit and its Complaint should be dismissed. As LivaNova will not join any lawsuit against itself, the Court’s dismissal should be with prejudice.

**Second**, notwithstanding the fact that DiLorenzo lacks standing to bring this lawsuit without joining LivaNova as a plaintiff, the Court should also dismiss DiLorenzo’s Complaint with prejudice for lack of standing because DiLorenzo is attempting to assert rights it does not own. Namely, DiLorenzo has filed suit for infringement of the Asserted Patents against LivaNova’s epilepsy treatment products, which fall squarely outside of DiLorenzo’s Field of Use. Each of the relevant agreements consistently display the parties’ intent to convey to LivaNova’s predecessors-in-interest rights to the Asserted Patents in the field of epilepsy treatment, and the Agreement containing the License Grant clearly conveys to DiLorenzo **only** a license in the field of treatment of obesity and metabolic disorders. Furthermore, Dr. DiLorenzo’s extensive correspondence with LivaNova and its predecessors regarding potential collaboration on projects relating to epilepsy treatment confirms that Dr. DiLorenzo has always known that he did not retain any rights to the Asserted Patents in epilepsy treatment.

Based on the evidence discussed, DiLorenzo lacks standing for its claims, and LivaNova respectfully requests the Court dismiss DiLorenzo’s Complaint with prejudice.<sup>1</sup>

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<sup>1</sup> Furthermore, based on the parties’ significant pre-suit correspondence on these issues, DiLorenzo knew its Rule 11 basis for filing the instant action was specious. LivaNova reserves all rights to request the Court order DiLorenzo to pay fees and costs under Fed. R. Civ. P. 11, 35 U.S.C. § 285, WASH. REV. CODE § 4.84.185 (1991), and *Octane Fitness LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 559 (2014).

## II. BACKGROUND

### A. Background of the Agreements and Patents

#### 1. Dr. Daniel J. DiLorenzo Conveyed His Rights in the Asserted Patents to LivaNova's Predecessor-in-Interest

In March 2004, Dr. DiLorenzo helped found NeuroBionics Corporation, a medical device company that focused on epilepsy treatment. [REDACTED]

[REDACTED], Dr. DiLorenzo assigned his rights in the Asserted Patents when he executed a “Founder Agreement” and, later, an “Amended and Restated Founder Agreement.” Ex. A (Mar. 31, 2004, Founder Agrmnt.); Ex. B (Dec. 14, 2004, Am. Founder Agrmnt.). Per those agreements, Dr. DiLorenzo assigned his rights in the ’813 patent *and all provisionals, continuations, partial continuations, and divisionals* to NeuroBionics. Ex. A, § 2(a), Schedule I; Ex. B, § 2(a); Schedule I. U.S. Patent Nos. 7,209,787 and 9,345,880 claim priority to the ’813 patent and are therefore covered by the assignment. *See* Dkt. 1-2 at field (63); Dkt 1-3, field (63). Dr. DiLorenzo also assigned any inventions he might make during his employment by NeuroBionics that either related to NeuroBionics’ business, resulted from tasks NeuroBionics assigned, or used NeuroBionics resources, and to promptly disclose all such work to NeuroBionics. Ex A, § 2(b); Ex. B, § 2(b). On December 14, 2004, Dr. DiLorenzo executed a broader “Assignment” conveying to NeuroBionics “all of the right, title and interest of the undersigned in and to any and all inventions, original works of authorship, developments, improvements, trade secrets, patents, patent applications, and other intellectual property, including clinical and preclinical data, related to [NeuroBionics’] business of neurodiagnostics and/or neuromodulation.” Ex. C (Dec. 14, 2004 Assignment to NeuroBionics).

On February 8, 2005, Dr. DiLorenzo and NeuroBionics entered a “Proprietary Information, Inventions Assignment, and Noncompete Agreement.” Ex. D. In the Proprietary Information,

Inventions Assignment, and Noncompete Agreement, Dr. DiLorenzo agreed “promptly to disclose to [NeuroBionics], during and after [his] employment, all Inventions and Works” that Dr. DiLorenzo invents during the term of his employment. *Id.*, § 4(b). “Company Inventions and Works” is defined as any invention that “pertain[s] to any actual or projected line of business activity of [NeuroBionics]; (ii) are aided by the use of time, material, facilities, or trade secrets of [NeuroBionics]; or (iii) relate to any of my work during the period of my employment by [NeuroBionics].” *Id.* This section also assigns to NeuroBionics “all right, title, and interest that [Dr. DiLorenzo has] or may acquire in such [NeuroBionics] Inventions and Works.” *Id.* Exhibit A to the agreement contains a list of all “Inventions and Works . . . that may be relevant to [NeuroBionics’] actual or projected business.” *Id.*, § 4(c).

## **2. NeuroBionics Successor, BioNeuronics, Granted DiLorenzo’s Company Limited Rights to the Asserted Patents in His Field of Use**

On May 23, 2005, BioNeuronics (the successor-in-interest to NeuroBionics and a predecessor-in-interest of LivaNova) entered into an “Exclusive License Agreement and Amendments to Founder Agreement, Assignment Agreement and Proprietary Information, Inventions Assignment and Noncompete Agreement” (hereinafter, “the Agreement”) with DiLorenzo Biomedical, LLC and Dr. DiLorenzo. Ex E. The Agreement codifies that on December 14, 2004, Dr. DiLorenzo assigned to NeuroBionics U.S. Patent No. 6,366,813 and its progeny, which by then included U.S. Patent Application No. 10/718,248, filed on November 20, 2003, which later issued as U.S. Patent No. 7,209,787 (asserted here) and which later included U.S. Patent No. 9,345,880.

The Agreement states that its goal is to clarify the previous agreements and to return to DiLorenzo a narrow scope of rights to “obesity and metabolism.” *See* Ex. E, 2. Specifically, Section 4 of the Agreement is the License Grant from BioNeuronics to DiLorenzo’s limited

liability company, DiLorenzo Biomedical LLC (defined as the sole “Licensee”), to “make use, sell, offer for sale, import, export and sublicense devices and methods for sympathetic nervous system modulation therapy and for neuromodulation therapy *for treating obesity and other metabolic disorders . . .*” (the “Field of Use”). *Id.*, § 4. The License Grant does not contain a right to sue for patent infringement. *Id.* Rather, Section 10 of the Agreement lays out the requirements for bringing patent infringement actions against others. *Id.*, § 10.

### **3. In April 2006, Dr. DiLorenzo Ceased Working for BioNeuronics**

On April 18, 2006, Dr. DiLorenzo and BioNeuronics executed a “Separation Agreement,” which reaffirmed that certain obligations continue through Dr. DiLorenzo’s separation from BioNeuronics. Ex. F, § 7. This includes the Assignment of Intellectual Property obligations of Section 2 of the Amended Founders Agreement (Ex. B, § 2) and Dr. DiLorenzo’s license agreement in favor of BioNeuronics in the field of epilepsy in the Inventions Agreement. Ex. D. The Separation Agreement also “specifically acknowledges” that the Agreement between the parties contains “a perpetual, fully paid up, worldwide, exclusive license to make, use, sell, offer for sale, import, export and sublicense *devices and methods for the treatment, diagnosis or amelioration of epilepsy and/or the symptoms thereof.*” Ex. F, § 7.3. This section further describes the grant-back in Section 4 of the Agreement as related to “certain rights and licenses in the Field of Use of *treating obesity and other metabolic disorders.*” *Id.*

The Separation Agreement also reiterates that the “actual or projected line of business activity of [BioNeuronics]” means “Inventions and Works that pertain to *neurological monitors, neurological stimulators, monitoring and stimulation leads, and medical telemetry apparatus that may be used with neurological monitors and neurological stimulators to diagnose, monitor and/or manage neurological and physiological disorders,*” except for Inventions and Works “in the field of autonomic modulation and neuromodulation *for obesity and metabolism.*” *Id.*, § 8.1.

## B. LivaNova Owns the '880 Patent

*Before* Dr. DiLorenzo separated from BioNeuronics, Dr. DiLorenzo filed U.S. Patent Application No. 11/333,979 on January 17, 2006, which later issued as U.S. Patent No. 9,345,880. Dkt. 1-3, fields (22), (21), (10). The '880 patent is titled “Closed-Loop Feedback-Driven Sympathetic Neuromodulation for Affect Control” and lists Daniel John DiLorenzo as both the Inventor and the Assignee. *Id.*, fields (54), (75), (73). The '880 patent’s “Related U.S. Application Data” shows that the '880 patent is a continuation-in-part of '787 and '813 patents. *Id.*, field (63).

As stated in every agreement, Dr. DiLorenzo was required to disclose to BioNeuronics any invention relating to BioNeuronics’ business (devices and methods for the treatment, diagnosis, or amelioration of epilepsy). Ex. A, § 2(b); Ex. B, §§ 2(b), 2(c); Ex C; Ex. D, § 4(b); *see generally* Ex. E; Ex. F, §§ 7.3, 8.2. The Agreement also codifies the prior assignment of U.S. Patent No. 6,366,813 and “Provisional Applications, Continuations and Continuations in Part naming U.S. Patent No. 6,366,813 or any of its filings as the parent case.” Ex. E, pg. 1. LivaNova thus owns the '880 patent because the '880 patent names the '813 patent as the parent case.

Furthermore, Dr. DiLorenzo should have disclosed the '880 patent to BioNeuronics and executed an assignment of the '880 patent to BioNeuronics. According to the Complaint, the '880 patent “has provided a significant advantage in the field of nerve stimulation therapy, as practiced by Defendants, in the case of the Accused Products, resulting in more effective treatment of **drug-resistant epilepsy in reducing the frequency and length of seizures.**” Dkt. 1, ¶ 21. The Complaint identifies the LivaNova Aspire SR<sup>TM</sup> (Model 106), SenTiva<sup>TM</sup> (Model 1000), and SenTiva Duo<sup>TM</sup> (Model 1000-D) VNS Therapy<sup>TM</sup> systems as the “Accused Products,” all of which are products used to treat epilepsy. *Id.*, ¶ 2. Therefore, by DiLorenzo’s assertions of the '880 patent against LivaNova’s epilepsy treatment products, Dr. DiLorenzo has stated that the '880 patent relates to

the field of epilepsy treatment and should have been disclosed and a formal assignment executed to BioNeuronics.

**C. Correspondence between Dr. DiLorenzo and LivaNova’s Predecessor-in-Interest Confirms DiLorenzo’s Narrowly Held Interest**

Cyberonics is a medical device company specializing in epilepsy treatment through stimulation of the Vagus nerve. Cyberonics acquired BioNeuronics’ patent portfolio (which included the Asserted Patents) in 2012, making Cyberonics the successor-in-interest to the Asserted Patents. Ex. I. On March 13, 2013, Dr. DiLorenzo sent correspondence to Cyberonics inquiring as to its “[REDACTED]” and whether Cyberonics would “[REDACTED] [REDACTED] [REDACTED].” Ex. J. As part of that conversation, in an April 22, 2013 email, Dr. DiLorenzo acknowledged that “the IP is divided along fields of use, ***mine being metabolism and autonomic structures*** (amygdala, hypothalamus, etc) and NeuroVista/Cyberonics being ***in epilepsy and other areas.***” *Id.*

Between August 2013 and November 2013, Dr. DiLorenzo corresponded with the then-General Counsel of Cyberonics. Ex. K. On August 25, 2013, Dr. DiLorenzo suggested [REDACTED]  
[REDACTED]. *Id.* Following additional correspondence, Cyberonics responded on September 23, 2013, clarifying that Dr. DiLorenzo only has rights relating to its Field of Use, and that Dr. DiLorenzo lacked the requisite standing to maintain a legal action for patent infringement without Cyberonics’ consent. *Id.* Dr. DiLorenzo did not respond to contest these points. *Id.*

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<sup>2</sup> Following Dr. DiLorenzo’s separation from BioNeuronics, BioNeuronics changed its name to “NeuroVista.”

**D. Correspondence between Dr. DiLorenzo and LivaNova Further Confirms DiLorenzo’s Narrowly Held Interest**

Cyberonics merged with the Sorin Group in 2015 and later underwent a name change to “LivaNova USA Inc.” On November 18, 2020, an attorney for Dr. DiLorenzo sent correspondence to LivaNova. Ex. L. Dr. DiLorenzo’s attorney stated that Dr. DiLorenzo [REDACTED]  
[REDACTED]  
[REDACTED]. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].” *Id.*

Between June 2022 and August 2022, Dr. DiLorenzo sent further correspondence to LivaNova. Ex. M. Dr. DiLorenzo inquired about obtaining full rights in the intellectual property LivaNova “acquired as part of NeuroVista” and proposed that Dr. DiLorenzo ***purchase*** the patents ***from LivaNova***. *Id.* On July 8, 2022, Dr. DiLorenzo offered [REDACTED] to purchase the patents formerly owned by NeuroBionics from LivaNova, with a [REDACTED] payment for the option to purchase. *Id.* After further discussion, Dr. DiLorenzo ***agreed to increase his offer and pay LivaNova*** [REDACTED] for the intellectual property with a [REDACTED] option lasting five years. Dr. DiLorenzo sent an Option Agreement summarizing these terms dated December 1, 2022. Ex. N. In that Option Agreement, Dr. DiLorenzo acknowledged that “[LivaNova] has not itself ever made, offered for sale, or sold any patented articles covered by the [patents] in the United States, nor imported any patented article covered by the [patents] into the United States.” *Id.*, § 4(c).<sup>3</sup>

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<sup>3</sup> This and other correspondence between the parties shows that, in addition to lacking standing to bring this lawsuit, Dr. DiLorenzo and DiLorenzo understand that LivaNova’s products do not infringe the Asserted Patents.

### **III. LEGAL STANDARDS**

Standing to sue is a prerequisite to federal subject matter jurisdiction. Only the patent owner (or, in some cases, an exclusive licensee) may sue for damages; suits by others must be dismissed for lack of standing. *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1551–52 (Fed. Cir. 1995) (*en banc*). Where a “licensee does not hold all substantial rights [in a patent], it may ‘sue third parties only as a co-plaintiff with the patentee.’” *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1382–83 (Fed. Cir. 2014). The plaintiff bears the burden of pleading and proving that it has standing to assert its claim. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207–10 (2021). Standing is for the Court to decide. *DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290–91 (Fed. Cir. 2008) (“The sole jury trial issue in this case concerns whether DDB is entitled to a jury trial on the jurisdictional issue of standing. We hold that it is not.”).

### **IV. ARGUMENT**

DiLorenzo was required to join LivaNova as a co-plaintiff in this action because DiLorenzo only has rights as a licensee in a limited field of use. Because DiLorenzo failed to do so, and because LivaNova will not join this lawsuit as a plaintiff against itself, the Court must dismiss DiLorenzo’s Complaint with prejudice for lack of standing. The Court should also dismiss DiLorenzo’s Complaint with prejudice for lack of standing because DiLorenzo is attempting to assert rights it does not own. Namely, DiLorenzo has filed suit for infringement of the Asserted Patents against LivaNova’s epilepsy treatment products, which fall squarely outside of DiLorenzo’s Field of Use.

**A. The Court Should Dismiss DiLorenzo’s Complaint for Failure to Join LivaNova as a Plaintiff**

DiLorenzo was required to add LivaNova as a plaintiff in this action and, in failing to do so, lacks standing to file this action. “The Supreme Court has long recognized that an exclusive licensee cannot sue for infringement without joining the patent owner if the license grants merely ‘an undivided part or share of the[e] exclusive right [granted under the patent].’” *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383–84 (Fed. Cir. 2015) (citing *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891)).

The facts of *Alps South* are instructive here. In *Alps South*, an inventor assigned a patent to a company he created (“AEI”). *Id.* at 1381. AEI then licensed certain rights in the patent for a particular “field of use” to the plaintiff, Alps. *Id.* at 1381, 1383. Alps then sued defendant Ohio Willow Wood (“OWW”) for infringement, relying on its license in the field of use (which included the right to sue) as its basis for standing. *Id.* Because Alps failed to join AEI as a co-plaintiff, OWW filed a motion to dismiss for lack of standing. *Id.* at 1381. The district court originally denied OWW’s motion to dismiss, finding the terms of the license (which granted Alps the right to sue for patent infringement in its field of use) were sufficient to provide Alps with standing. *Id.* Shortly before trial, the district court *sua sponte* reconsidered the standing issue and invited Alps to join AEI as a co-plaintiff. *Id.* at 1382. Alps declined, and despite the district court’s concerns, the case proceeded to trial, after which a jury found the patent valid and infringed. *Id.*

OWW appealed, arguing the license to Alps did not convey sufficient rights to confer standing without joining AEI as a co-plaintiff. *Id.* The Federal Circuit agreed, finding that “the original agreement’s field of use restriction [was] fatal to Alps’s argument that it had standing to file this action.” *Id.* at 1383. The Federal Circuit explained that “finding that a field of use licensee has standing ‘to sue in its own name alone poses a substantial risk of multiple suits and multiple

liabilities against an alleged infringer for a single act of infringement.”” *Id.* at 1384 (citing *Int’l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1278 (Fed. Cir. 2007)). Federal Circuit standing jurisprudence, therefore, “compels an exclusive licensee with less than all substantial rights, *such as a field of use licensee*, to join the patentee before initiating suit.” *Id.* (citing *Int’l Gamco*, 504 F.3d at 1278 (internal quotations omitted; emphasis original)). The Federal Circuit held that “[b]ecause the license restricted Alps’s rights in the ’109 patent to the field of [use], Alps lacked standing to pursue this litigation without naming AEI as a co-plaintiff.” *Id.*

Nearly identical circumstances are present here. In 2004, Dr. DiLorenzo assigned all rights in the Asserted Patents to LivaNova’s predecessors-in-interest. *See generally* Ex. B, Ex. C. BioNeuronics granted back to DiLorenzo “a perpetual, fully paid up, worldwide, exclusive license to make, use, sell, offer for sale, import, export and sublicense devices and methods for sympathetic nervous system modulation therapy and for neuromodulation therapy for treating obesity and other metabolic disorders (hereinafter referred to as the Field of Use), which inventions are covered by one or more claims of the Assigned Patents.” Ex. E, § 4. Thus, DiLorenzo only owns a license to make, use, sell, offer for sale, import, export, and sublicense devices and methods in the Field of Use of the Asserted Patents. Importantly, the License Grant does not include a right to sue for patent infringement. Procedures for bringing a lawsuit for patent infringement are governed by Section 10 of the Agreement, including acknowledging that LivaNova may need to be named as a plaintiff in a patent infringement lawsuit to maintain standing. *Id.*, § 10.

DiLorenzo acknowledges in the Complaint that it is only a licensee in a field of use: “LivaNova’s predecessor-in-interest, BioNeuronics Corporation, granted DiLorenzo Biomedical’s predecessor-in-interest, in its successors and assigns, an exclusive license” to the Asserted Patents ***within an “Exclusive Field of Use.”*** Dkt. 1, ¶ 15. Therefore, because DiLorenzo is a “licensee

with less than all substantial rights,” DiLorenzo was compelled “to join the patentee[, LivaNova,] before initiating suit.” *Int’l Gamco*, 504 F.3d at 1278. DiLorenzo failed to do so. Because LivaNova does not consent to be joined as a plaintiff against itself in this action, the Court should dismiss DiLorenzo’s Complaint with prejudice.

The facts here also do not meet the criteria for the limited exception to this rule, that “an exclusive licensee that does not have all substantial rights does have standing to sue in his own name when ‘necessary to prevent an absolute failure of justice, as where the patentee is the infringer, and cannot sue himself.’” *Textile Prods., Inc. v. Mead Corp.*, 134 F. 3d 1481, 1484 (Fed. Cir. 1998). First, the License Grant does not include a right to sue. Rather, the right to sue (for both parties) is governed by Section 10 of the Agreement. Ex. E, § 10. In fact, Section 10 of the Agreement acknowledges that LivaNova may be required to be joined to any patent infringement suit as a party for standing purposes. *Id.*, § 10(c). Only when certain conditions are met is DiLorenzo allowed to bring a suit for patent infringement. *Id.* Second, despite the use of the term, DiLorenzo is ***not*** an exclusive licensee as to the entire set of rights in the Asserted Patents but only a licensee to make and sell products in its “Field of Use,” which, as discussed below, unquestionably ***does not*** include products for the treatment of epilepsy.

**B. The Court Should Dismiss DiLorenzo’s Complaint for Lack of Standing Because DiLorenzo Has No Ownership Rights Outside the Narrow “Field of Use” of Treating Obesity and Metabolic Disorders**

Should the Court not dismiss DiLorenzo’s Complaint for failure to join LivaNova, the Court should dismiss DiLorenzo’s Complaint for lack of standing because DiLorenzo’s rights are limited to DiLorenzo’s narrow Field of Use for treating obesity and metabolic disorders. DiLorenzo’s Complaint is predicated on an inaccurate interpretation of the License Grant. Namely, DiLorenzo’s position is that the License Grant conveyed to DiLorenzo rights in the Asserted Patents “for sympathetic nervous system modulation therapy” ***and separately***

“neuromodulation therapy for treating obesity and other metabolic disorders.” Based on this read of the License Grant, DiLorenzo argues LivaNova’s products are products “for sympathetic nervous system modulation therapy” that meet the claims of the Asserted Patents. Putting aside whether LivaNova’s products are products “for sympathetic nervous system modulation therapy” (which they are not), such a read of the License Grant cannot stand, as it would defeat the objectives of the Agreement and the parties’ previous agreements, as discussed below.

Under Washington law, courts interpret a contract in accordance with the “context rule.”<sup>4</sup> *Microsoft Corp. v. Motorola, Inc.*, 864 F. Supp.2d 1023, 1033 (W.D. Wash. 2012). Under the context rule, extrinsic evidence is admissible to assist the court in ascertaining the parties’ intent and interpreting the contract. *Id.* “The court may consider (1) the subject matter and objective of the contract, (2) the circumstances surrounding the making of the contract, (3) the subsequent conduct of the parties to the contract, (4) the reasonableness of the parties’ respective interpretations, (5) statements made by the parties in preliminary negotiations, (6) usages of trade, and (7) the course of dealing between the parties.” *Id.* Such evidence is admissible regardless of whether the contract is deemed ambiguous. *Id.* Based on an analysis of these factors, it is clear that the Field of Use means “for sympathetic nervous system modulation therapy and for neuromodulation therapy” **both** “for treating obesity and other metabolic disorders.” DiLorenzo’s rights are limited to the Field of Use of treating obesity and other metabolic disorders and cannot be used to maintain an action against the accused products, which are used to treat epilepsy.

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<sup>4</sup> Section 20 of the Agreement states that the “Agreement shall be governed and enforced in accordance with laws of the state of Washington.” Ex. E, § 20.

## 1. The Subject Matter, Objective, and Circumstances Surrounding the Making of the Contract Support LivaNova's Position

The subject matter, objective, and circumstances surrounding the making of the Agreement support LivaNova's position that the License Grant is limited to the Field of Use of treating obesity and metabolic disorders through the use of sympathetic nervous system modulation therapy and neuromodulation therapy. Page one of the Agreement confirms that DiLorenzo assigned to BioNeuronics "U.S. Patent No. 6,366,813 . . . and Provisional Applications, Continuations and Continuations in Part naming US Patent No. 6,366,813 or any of its filings as the parent case" (the "Assigned Patents"), which is a family of patents relating to epilepsy treatment. Ex. E, pg. 1. Page one of the Agreement also reiterates that DiLorenzo's assignment excluded certain patents (***not*** in the family of the '813 patent) relating to "Autonomic Modulation and Neuromodulation for Obesity & Metabolism." *Id.* Page two of the Agreement further explains that, in part, the purpose of the Agreement is to accomplish the parties' goal of using "their best efforts" to "grant back to DiLorenzo certain of the assigned intellectual property ***relating to obesity and metabolism.***" Ex. E, pg. 2. This establishes that DiLorenzo only intended to retain for himself rights in his patents insofar as they relate to the treatment of obesity and metabolism. The License Grant itself states that DiLorenzo was granted an "exclusive license to make, use, sell, offer for sale, import, export and sublicense devices and methods for sympathetic nervous system modulation therapy and for neuromodulation therapy ***for treating obesity and other metabolic disorders*** (hereinafter referred to as the Field of Use), which inventions are covered by one or more claims of the Assigned Patents." Ex. E, § 4.

Other clauses in the early agreements between Dr. DiLorenzo, NeuroBionics, and BioNeuronics confirm the parties' objectives were to assign to NeuroBionics all inventions and

intellectual property relating to the treatment of epilepsy and to only allow DiLorenzo to retain the same in the field of treatment of obesity and metabolic disorders. Specifically:

- The Founder Agreement requires that Dr. DiLorenzo assign any invention that “*relates to the business of the Company*.” Ex. A, § 2(b). NeuroBionics’ business was the treatment of epilepsy. *See, e.g.*, Ex. C.
- In the Amended and Restated Founder Agreement, Dr. DiLorenzo carves out certain inventions relating to “Autonomic Modulation and Neuromodulation for ***Obesity & Metabolism***,” showing Dr. DiLorenzo only intended to retain rights in intellectual property relating to the treatment of obesity and metabolism, not epilepsy treatment. Ex. B, § 2(b).
- The Amended and Restated Founder Agreement assigns any invention by Dr. DiLorenzo relating to ***NeuroBionics’ business*** (epilepsy treatment) to NeuroBionics. Ex. B, §§ 2(b), 2(c).
- The Assignment by Dr. DiLorenzo to NeuroBionics Corporation lists NeuroBionics business as “*neurodiagnostics and/or neuromodulation*.” Ex. C.
- The Inventions Assignment requires that Dr. DiLorenzo assign any invention relating to “*any actual or projected line of business activity of the Company*” (epilepsy treatment) to BioNeuronics. Ex. D, § 4.

The objectives of the Agreement and the License Grant are clear. The parties wished to (1) confirm the assignment of the ’813 and its progeny to BioNeuronics; (2) confirm DiLorenzo’s retention of certain unrelated patents relating to the field of obesity and metabolic disorders; and (3) grant to DiLorenzo a ***new right*** to the Asserted Patents in the field of treating obesity and metabolism. The context of the subject matter and objective of the Agreement and earlier agreements show that through the License Grant, the parties intended to convey to DiLorenzo rights to the Asserted Patents ***only*** in the field of treating obesity and metabolism.

Nothing in the Agreement supports DiLorenzo’s interpretation, which is that the License Grant conveyed to DiLorenzo rights in “sympathetic nervous system modulation therapy” (for the treatment of epilepsy or otherwise) ***and separately*** “neuromodulation therapy for treating obesity and other metabolic disorders.” In other words, DiLorenzo is arguing that BioNeuronics retained

the rights to the Asserted Patents for the treatment of epilepsy through the *parasympathetic* nervous system but not the *sympathetic* nervous system. DiLorenzo can point to no evidence that would support any intent by BioNeuronics to give away any of its rights to the Asserted Patents for the treatment of epilepsy, let alone divided along the lines of sympathetic versus parasympathetic neuromodulation therapy. In fact, such an interpretation would *defeat* the objectives of the Agreement, which were clearly to grant to BioNeuronics all rights in the Asserted Patents for use in the treatment of epilepsy.

Thus, the subject matter, objective, and circumstances surrounding the Agreement show DiLorenzo's license in the "Field of Use" clearly means "for sympathetic nervous system modulation therapy and for neuromodulation therapy" *both* "for treating obesity and other metabolic disorders."

## **2. The Subsequent Conduct and Course of Dealing Between the Parties to the Contract Support LivaNova's Position**

LivaNova's position that "Field of Use" means "for sympathetic nervous system modulation therapy and for neuromodulation therapy" *both* "for treating obesity and other metabolic disorders" is also supported by a wealth of evidence following the execution of the Agreement. In particular, the Separation Agreement executed after the Agreement and the parties' later correspondence show that DiLorenzo knew it only had rights to the Asserted Patents in the limited Field of Use of treating obesity and metabolic disorders.

The Separation Agreement reiterates that the "actual or projected line of business activity of [BioNeuronics]" means "Inventions and Works that pertain to neurological monitors, neurological stimulators, monitoring and stimulation leads, and medical telemetry apparatus that may be used with neurological monitors and neurological stimulators to diagnose, monitor and/or manage neurological and physiological disorders, except for Inventions and Works "in the field of

autonomic modulation and neuromodulation for obesity and metabolism.” *Id.*, § 8.1. It also describes Dr. DiLorenzo’s “Field of Use” as “*treating obesity and other metabolic disorders.*” *Id.*, § 7.3. Again, there is no reference to DiLorenzo retaining any rights whatsoever relating to the treatment of epilepsy, much less any division of rights along the lines of sympathetic versus parasympathetic neuromodulation. On the contrary, the Separation Agreement again draws the line of the parties’ rights between the treatment of epilepsy and other physiological disorders, and the treatment of obesity and metabolism. The Separation Agreement further confirms LivaNova’s interpretation of the License Grant.

Dr. DiLorenzo also had significant correspondence with LivaNova and its predecessor-in-interest, Cyberonics, relating to parties’ rights in the Asserted Patents. All of this correspondence supports LivaNova’s interpretation of the License Grant, and none of it supports DiLorenzo’s.

On March 13, 2013, Dr. DiLorenzo sent Cyberonics follow-up correspondence in which Dr. DiLorenzo acknowledged that “the IP is divided along fields of use, mine being metabolism and autonomic structures (amygdala, hypothalamus, etc) and [NeuroBionics]/Cyberonics being in epilepsy and other areas.” Ex. J. Dr. DiLorenzo’s correspondence with Cyberonics confirms that Dr. DiLorenzo understood the fields of use to be divided along the lines of “metabolism and autonomic structures” and “epilepsy and other areas,” and that those rights did *not* cover Cyberonics’ vagus nerve stimulation devices, which treat epilepsy. This is consistent with the parties original agreements, and further confirms that the intent of those agreements was to divide the rights in the Asserted Patents between epilepsy treatment and the treatment of obesity and metabolic disorders.

Beginning in November 2020, Dr. DiLorenzo began contacting LivaNova with the goal of

[REDACTED] . Ex. L. On November

18, 2020, Dr. DiLorenzo's counsel, Stanley Gibson, sent correspondence to LivaNova stating Dr.

DiLorenzo [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED]. Ex. K, pg. 7, 8. Dr. DiLorenzo requested that LivaNova [REDACTED]

[REDACTED]. Ex. L. However, if LivaNova was not [REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED] *Id.* In other words, Dr. DiLorenzo **knew** that he did not have rights in the patents relating to the field of epilepsy treatment or the right to bring a patent infringement lawsuit without the consent of LivaNova.

Beginning in June 2022, Dr. DiLorenzo sent correspondence to LivaNova, requesting to purchase the NeuroBionics patents **from LivaNova** so that Dr. DiLorenzo could pursue [REDACTED]. Ex. M. On July 8, 2022, Dr. DiLorenzo offered [REDACTED] to purchase the patents formerly owned by NeuroBionics from LivaNova, with a [REDACTED] payment for the option to purchase. *Id.* After further discussion, Dr. DiLorenzo **agreed to increase his offer and pay LivaNova** [REDACTED] for the intellectual property with a [REDACTED] option lasting five years. Dr. DiLorenzo sent an Option Agreement summarizing these terms dated December 1, 2022. Ex. N. This reaffirms that Dr. DiLorenzo knew he did not have full rights in the Asserted Patents and was willing to pay LivaNova to secure those rights.

Finally, Dr. DiLorenzo's silence relating to any alleged infringement by LivaNova speaks volumes. As previously explained, the parties corresponded for years relating to Dr. DiLorenzo's limited rights in the Asserted Patents. *See generally* Ex. G; Ex. J; Ex. K; Ex. L and Ex. M. This

included colloquial correspondence regarding Cyberonics' business of epilepsy treatment, as well as more serious correspondence sent by Dr. DiLorenzo's attorney relating to his limited rights in the Asserted Patents and a request to pursue patent litigation against a third party. *Id.* Never, in over a decade of correspondence with LivaNova and its predecessors, did Dr. DiLorenzo suggest that he had rights in the field of epilepsy treatment (or even outside the field of treating obesity and metabolic disorders) or that LivaNova's products may infringe DiLorenzo's limited rights in the Asserted Patents. On the contrary, Dr. DiLorenzo's own statements show that (1) Dr. DiLorenzo understood he did not have rights in the Asserted Patents relating to the treatment of epilepsy and was therefore required to join LivaNova as a plaintiff in any patent infringement lawsuit relating to products that treat epilepsy; (2) the rights in the intellectual property were divided between "metabolism and autonomic structures" and "epilepsy and other areas," and (3) in order to obtain full rights in the Asserted Patents, he would have to purchase those rights from LivaNova. Only after Dr. DiLorenzo's attempt to purchase the Asserted Patents (and relatedly, [REDACTED]) fell through did Dr. DiLorenzo threaten (and ultimately file) litigation against LivaNova. Thus, the subsequent conduct and course of dealing between Dr. DiLorenzo and LivaNova shows that even Dr. DiLorenzo understands his recently formed interpretation of the License Grant is untenable.

### **3. The Reasonableness of LivaNova's Interpretation (and Unreasonableness of DiLorenzo's Interpretation) Support LivaNova's Position**

Finally, the unreasonableness of DiLorenzo's interpretation of the License Grant supports LivaNova's position that DiLorenzo's Field of Use only relates to the treatment of obesity and metabolic disorders. *First*, DiLorenzo's interpretation of the License Grant in the Agreement would frustrate the intent of the Agreement, and all the agreements before it. Multiple clauses in each of the agreements explain that BioNeuronics' business related to the treatment of epilepsy

and that Dr. DiLorenzo was required to, and did, assign to BioNeuronics all rights in any inventions or intellectual property relating to BioNeuronics' business. If the objective of all of the agreements was to convey to BioNeuronics inventions and intellectual property for purposes of developing epilepsy treatments, why would BioNeuronics grant a license to DiLorenzo for that exact right?

**Second**, DiLorenzo's interpretation of the License Grant would read into the agreements a division of the intellectual property rights in epilepsy treatment between sympathetic nervous system neuromodulation therapy and parasympathetic nervous system neuromodulation therapy. Nowhere in any of the agreements do the parties discuss the sympathetic and parasympathetic systems, much less delineate between the two for purposes of dividing intellectual property rights. Every pertinent agreement states or reiterates that BioNeuronics' business was the treatment of epilepsy, not the treatment of epilepsy solely through neuromodulation of the parasympathetic nervous system.

As such, DiLorenzo knows and has known for nearly two decades that he does not have rights in the field of the treatment of epilepsy and does not have standing to bring this lawsuit.

## V. CONCLUSION

As shown above, DiLorenzo lacks standing to bring this suit against LivaNova because DiLorenzo failed to join LivaNova as a plaintiff, as required by Supreme Court and Federal Circuit precedent. DiLorenzo further lacks standing to bring this suit because DiLorenzo does not have rights to the Asserted Patents in the field of epilepsy treatment. DiLorenzo's Complaint should be dismissed with prejudice.

Dated: October 16, 2023

Respectfully submitted,

FISH & RICHARDSON P.C.

By: /s/ Benjamin C. Elacqua

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**CERTIFICATE OF CONFERENCE**

The undersigned hereby certifies that counsel for LivaNova, Benjamin Elacqua and Kathryn Quisenberry, met and conferred with counsel for DiLorenzo Biomedical LLC, David Liston, Ron Abramson, and Alex Patchen, met and conferred on October, 6 2023. Plaintiff indicated that it is opposed to this motion.

/s/ Benjamin C. Elacqua

Benjamin C. Elacqua

**CERTIFICATE OF SERVICE**

The undersigned attorney hereby certifies that on October 16, 2023, a true and correct copy of the foregoing document was served via electronic mail on all counsel of record.

/s/ Benjamin C. Elacqua

Benjamin C. Elacqua